January 24, 2005

VIA ELECTRONIC SUBMISSION
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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Docket No. 2004D-0369

Pioneer Hi-Bred International, Inc. comments on the FDA Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use.

To Whom It May Concern:

Pioneer Hi-Bred International, Inc., a DuPont company, (Pioneer) develops and markets improved seed products that ensure the competitiveness of American farmers and growers, who provide the consumer with a varied selection of safe, nutritious and reasonably priced foods. We are engaged in research and product development activities designed to further enhance the quality, variety, productivity and availability of agricultural seeds. Our scientists use a combination of conventional methods of plant breeding and modern biotechnology to develop improved plant varieties. Pioneer supports sound science-based and risk-focused regulation that encourages high production standards and promotes public confidence in the health and environmental safety of new crop varieties from which our food products are developed.

Pioneer is committed to the development of new biotechnology-derived food crops in compliance with appropriate crop isolation procedures and agricultural practices which minimize the potential for inadvertent, intermittent, low-level presence of proteins in the food supply prior to the premarket review process.

Pioneer renews its support for the premarket biotechnology notification (PBN) rule proposed by FDA on January 18, 2001 (66 Fed. Reg. 4706). Pioneer urges FDA to finalize that rule at the earliest possible time. The PBN Rule would formalize a procedure for the submission and review of premarket notifications for biotechnology-derived foods, enhance the transparency of the review process and address FDA's enforcement authority as it applies to biotechnology-derived food that might be marketed without satisfactory completion of the PBN process. Prompt action to finalize the PBN Rule is needed to further strengthen U.S. government policy related to biotechnology, reassure the public, food and commodity groups, agricultural interests and food export

markets of the safety of all biotechnology-derived foods grown in the U.S., and to ensure the safety of the domestic food supply, particularly with respect to future imports from developing nations.

Pioneer is responding to FDA's notice of availability of the FDA Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use, in the November 24, 2004 Federal Register (69 FR 68381).

Comments on the Draft Guidance

General Comments

Pioneer is pleased with FDA's science-based evaluation which focuses on the early assessment for potential allergenicity or toxicity of an introduced protein which had been proposed by the Office of Science and Technology Policy (OSTP) in August 2002 (67 FR 50578). While the Draft Guidance refers to the OSTP Notice, Pioneer encourages FDA to clearly state the underlying principles outlined in the OSTP Notice used in developing updated field test requirements by USDA/APHIS and this guidance for early food safety evaluation of new proteins introduced into food crops. Additionally, Pioneer encourages FDA to refer to complementary activities at EPA and USDA/APHIS which, together with FDA's early food safety evaluation will ensure timely safety evaluation of introduced proteins (both pesticidal and non-pesticidal) and minimize the potential for inadvertent, intermittent low-level presence of introduced proteins in the food and feed supply.

Pioneer believes FDA must maintain some flexibility in data requirements as the types of traits, technology, and methods to assess safety continue to evolve. Development of safety information should be scientifically sound and appropriate for the trait and species under evaluation.

Definition of a New Protein

Pioneer believes that a protein introduced into a plant species that has previously been consumed and has a history of safe use, should not be subject to the early food safety evaluation. Pioneer believes that FDA should focus its resources on those non-pesticidal proteins that are truly new to a plant species used as food or feed. Accordingly, for the purposes of this Guidance, we urge FDA to amend its definition of a new protein to read:

> "A new protein refers to any non-pesticidal protein, that does not have a history of safe use in food or feed, produced in a crop plant, or is a native protein that has been produced at a significantly elevated level and has not been the subject of a completed biotechnology consultation or a completed early food safety evaluation with FDA."

Transparency

Pioneer supports FDA's provision of information regarding submission of, and FDA's response to, early food safety evaluations for new proteins that will be easily accessible to the public, consistent with confidentiality requirements of federal law. In addition, FDA should ensure that any information regarding safety evaluation is clearly and accurately characterized.

A combined list of proteins that have successfully completed both the FDA early food safety evaluation and EPA's safety evaluation for pesticidal proteins, accessible through the Internet, would be of value to developers, the general public and other regulatory authorities.

Codex Alimentarius Guideline

Pioneer supports the focus of the early safety evaluation on potential allergenicity and toxicity and the use of the Codex Alimentarius "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants" as guidance. The Codex Guideline is the internationally recognized standard for the conduct of food safety assessments for foods derived from biotechnology-derived plants and provides a framework for assessment of potential toxicity and allergenicity of a new substance.

FDA Review Period

Pioneer believes that the 120 days proposed by FDA in the Draft Guidelines is too long and recommends that FDA consider a 90-day review of early food safety evaluations, with the ability to extend an additional 30 days.

Comments on the Information Collection Request

Pioneer considers the proposed collection of information to be necessary for the proper performance of FDA's functions under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.), the Coordinated Framework for Regulation of Biotechnology (51 Fed. Reg. 23302, June 26, 1986), and the 1992 Statement of Policy: Foods Derived from New Plant Varieties.

New, Non-pesticidal Proteins

The scope of the proposed collection of information is appropriately limited to new, non-pesticidal proteins. EPA regulates pesticidal proteins as plant-incorporated protectants under the food safety provisions of Section 408 of the FFDCA (21 U.S.C. 346a), and under the permit and registration requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.).

Pioneer urges FDA to consider highly similar proteins that may differ by one or more amino acids but retain the same function to be a ‘family’ of proteins, and consider them under a single early food safety evaluation. Certain aspects of these proteins may be evaluated individually, such as sequence homology evaluation to known toxins or allergens, however, much of the information provided would be the same. Therefore, early food safety evaluation for such a group of highly homologous proteins should be contained within a single submission, thereby making efficient use of FDA resources in the evaluation.

Pioneer appreciates the opportunity to offer these comments.

Sincerely,

Steven Daugherty
Director, Pioneer Biotechnology Affairs